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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,136	07/20/2001	John D Fraser	3911-8	1247

7590 08/24/2004  
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EXAMINER

MINNIFIELD, NITA M

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/869,136

**Applicant(s)**

FRASER ET AL.

**Examiner**

N. M. Minnifield

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 5/19/04.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.  
4a) Of the above claim(s) 3-13 and 15-30 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,2,14 and 31 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 3-13 and 15-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 2 sheets  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' amendment filed May 19, 2004 is acknowledged and has been entered. Claims 1, 2, 14 and 31 have been amended. Claims 1, 2, 14 and 31 are now pending and being examined in the present application. All rejections have been withdrawn in view of Applicants' amendment with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. This application contains claims 3-13 and 15-30 drawn to an invention nonelected with traverse in Paper No. 11 (12/09/02). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Claims 1, 2 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The amendment to claims 1, 2 and 31 filed May 19, 2004 consist of new matter. The limitation of "wherein SMEZ-2 or a functionally equivalent variant of SMEZ-2 contains an amino acid sequence of KTSIP" is not found in the specification. There is no support found in the specification for a variant that specifically has

amino acid sequence KTSIP. The specification at page 1 and page 6 only disclose “a functionally equivalent variant thereof”. This contemplates that the functionally equivalent variant thereof can be a variant of any portion, segment or fragment of the SMEZ-2 as long as it has the function of SMEZ-2. The specification discusses the phrase “functionally equivalent variants”; recognizes that it is possible to vary the amino acid/nucleo-tide sequence of a peptide while retaining substantially equivalent functionality. For example, a peptide can be considered a functional equivalent of another peptide for a specific function if the equivalent peptide is immunologically cross-reactive with and has at least substantially the same function as the original peptide. The equivalent can be, for example, a fragment of the peptide, and a fusion of the peptide with another peptide or carrier, or a fusion of a fragment which additional amino acids. For example, it is possible to substitute amino acids in a sequence with equivalent amino acids using conventional techniques. Groups of amino acids normally held to be equivalent are:

- (a) Ala, Ser, Thr, Pro, Gly;
- (b) Asn, Asp, Glu, Gln;
- (c) His, Arg, Lys;
- (d) Met, Leu, Ile, Val; and
- (e) Phe, Tyr, Trp.

Nowhere in the specification does it specifically state nor suggest that the functionally equivalent variant thereof must have the amino acid sequence KTSIP, as presently set forth in the pending claims. The specification does not teach or enable a functionally equivalent variant thereof must have the amino acid sequence KTSIP.

5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is vague and indefinite in the recitation of “an amino acid sequence”; do Applicants intend for this to mean a fragment or portion of SEQ ID NO: 2 or the entire amino acid sequence of SEQ ID NO: 2?

6. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Kamezawa et al (Infection and Immunity, 1997).

The claim is directed to a method of subtyping Streptococci comprising providing a Streptococci sample to be tested, determining whether or not a superantigen SMEZ-2 having an amino acid sequence of SEQ ID NO:2 or a functionally equivalent variant is present in said sample; and subtyping the Streptococci on the basis of whether or not SMEZ-2 or a functionally equivalent variant is present.

Kamezawa et al discloses a SMEZ (streptococcal mitogenic exotoxin Z) superantigen from *Streptococcus pyogenes* (abstract). The prior art discloses that these superantigens have a molecular weight range of 25 to 30 kD, a pI of 7 and biological activities include mitogenicity and they act as superantigens to stimulate T cells to produce cytokines (p. 3828, column 1 and materials and methods). Kamezawa et al discloses the amino acid sequence of the superantigen (see figure 5, p. 3832; p. 3831). The prior art discloses the method of subtyping of Streptococcal proteins (materials and methods). “In the present study we provide evidence that A $\beta$  is not a subtype of ETA but is a unique superantigenic exotoxin,

being distinct not only from classical Ets but also from all the other mitogens or superantigens mentioned above.” (p. 3828, col. 2). With regard to the differences in the amino acid sequences, it is noted that the claims recite a SMEZ-2 superantigen having an amino acid sequence of SEQ ID NO: 2 *or* a functionally equivalent variant. It would appear that the superantigen taught in Kamezawa et al is a functionally equivalent variant of the superantigen having an amino acid sequence of SEQ ID NO: 2 (see figure 5) and that the prior art discloses a superantigen having an amino acid sequence of SEQ ID NO: 2 (see figure 5).

Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. It is also noted that claims 1, 2, 14 and 31 are only examined with regard to SEQ ID NO: 2/SMEZ-2, not the other non-elected and withdrawn species ((SPE-G, SPE-H and SPE-J) that are still recited in the claims. Applicants should cancel non-elected subject matter from claims 1, 2, 14 and 31.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

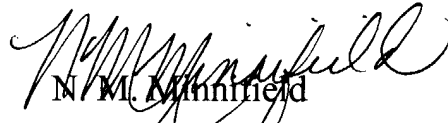
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
N. M. Minnifield  
Primary Examiner  
Art Unit 1645

NMM

August 16, 2004